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EXAMINER

MARTIN, J

ART UNIT

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

FIVE

Office Action SummaryApplication No.
08/465,596Applicant(s)
Richard F. SeldenExaminer
Jill D. MartinGroup Art Unit
1632☒ Responsive to communication(s) filed on Dec 28, 1999☐ This action is **FINAL**.☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims☒ Claim(s) 72-79, 82-84, and 104-106 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.☒ Claim(s) 72-79, 82-84, and 104-106 is/are rejected.☐ Claim(s) _____ is/are objected to.☐ Claims _____ are subject to restriction or election requirement.**Application Papers**☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.☐ The drawing(s) filed on _____ is/are objected to by the Examiner.☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.☐ The specification is objected to by the Examiner.☐ The oath or declaration is objected to by the Examiner.**Priority under 35 U.S.C. § 119**☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.☐ received in Application No. (Series Code/Serial Number) _____.☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).**Attachment(s)**☐ Notice of References Cited, PTO-892☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____☐ Interview Summary, PTO-413☐ Notice of Draftsperson's Patent Drawing Review, PTO-948☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Transitional After Final Practice

Since this application is eligible for the transitional procedure of 37 CFR 1.129(a), and the fee set forth in 37 CFR 1.17(r) has been timely paid, the finality of the previous Office action is hereby withdrawn pursuant to 37 CFR 1.129(a). Applicant's second submission after final filed on October 5, 1999, Paper No. 22, has been entered. Claims 80, 85-95, and 97-103 have been canceled, claim 72 has been amended, and claims 104-106 have been added.

Applicants' Supplemental Amendment filed December 28, 1999, Paper No. 23, has been entered. Claims 72 and 104 have been amended. Claims 72-79, 82-84, and 104-106 are pending and are under current examination.

Prior rejections of record not made of record in the instant Office action have been withdrawn in view of Applicants' arguments and/or amendments to the claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 72-79, 82-84, and 104-106 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 91-103, 106-108, and 129-131 of copending Application No. 08/461,292, over pending claim 44 of copending application Serial No. 08/460,902, and over claim 36 of co-pending application Serial No. 08/465,582. Although the conflicting claims are not identical, they are not patentably distinct from each other because each of the four co-pending applications contain claims to processes of implanting transfected cells where the transfected cells express DNA that was inserted into the cell prior to implantation. Here, expressing a DNA sequence in a cell to produce a product (a transfected cell preparation) for the intended use of transferring the DNA into a recipient subject is the same inventive concept as a method of using the transfected cells for transferring the DNA to the recipient subject, *i.e.*, the transfected cell preparations are required in the methods of transferring the DNA into a recipient subject. Moreover, in the copending '582 and '902 applications, introducing into a human, human cells which have been treated *in vitro* to insert DNA encoding a therapeutic protein, is encompassed within the method of transferring a gene to

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a recipient subject using the transfected cell preparations. As such, if Applicants intend for the instant claims to be a species of the '582 and '902 claims since the instant claims are specifically limited to transfection by chemical or physical techniques and the '582 and '902 claims are not so limited, then a genus ('582 and '902) always renders a species (the instant application, '292) obvious.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 72-79, 82-84, and 104-106 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 135-141, 143-154, and 156-164 of copending Application No. 08/334,797 in view of Salser et al. (US'796). Although the conflicting claims are not identical, they are not patentably distinct from each other because the presently claimed transfected cells are not distinguishable over the cells set forth in the above claims of the copending application. Both applications claim transfected cells where the cells of the copending application are obvious variations of the cells claimed in the present application. Furthermore, the disclosure of Salser et al. support that it would have been obvious to implant the transfected cells disclosed in the copending application such that an intended use for transferring a gene to a recipient (as recited in the present claims) would have been an obvious extension of use for the copending claims in view of Salser et al.

This is a provisional obviousness-type double patenting rejection.

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Claims 72-79, 82-84, and 104-106 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 5,994,127. Although the conflicting claims are not identical, they are not patentably distinct from each other because the presently claimed transfected cells are not distinguishable from the transfected cells set forth in the above claims of the '127 Patent. Both the present application and the US Patent claim transfected cells where the cells of the US Patent are obvious variations of the cells claimed in the present application. Therefore, the two applications claim the same inventive concept.

Claims 72-79, 82-84, and 104-106 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 08/446,909. Although the conflicting claims are not identical, they are not patentably distinct from each other because the co-pending application contains claims to processes of implanting transfected cells which are an obvious variant of the claimed transfected cells which are intended for use in transferring a gene to a recipient. Here, expressing a DNA sequence in a cell to produce a product (a transfected cell preparation) for the intended use of transferring the DNA into a recipient subject is the same inventive concept as a method of using the transfected cells for transferring the DNA to the recipient subject, *i.e.*, the transfected cell preparations are required in the methods of transferring the DNA into a recipient subject.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 72-79, 82-84, and 104-106 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-84 of U.S. Patent No. 5,968,502. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims require the intended use of the cell for transferring a gene to a recipient and the patented claims require providing a protein to a mammal by transfected cells which are obvious variants of the cells of the present application. Therefore, the present application and the US Patent claim the same inventive concept.

The prior provisional double patenting rejection of claims 72-79, 82-84, and 104-106 over the claims in the copending application 08/446,912 has been withdrawn in view of the abandonment of the '912 copending application.

Applicants' comments at pages 18-26 of the Amendment filed December 5, 1999, Paper No. 22, have been considered, however, are not persuasive.

Applicants' arguments appear to be based on the present claims concerning a species of the generic concept of *ex vivo* gene therapy claimed in the '582 and '902 applications, pointing to the newly added claim limitation "are incapable of causing rearrangement of endogenous genes

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and initiating chronic viral infection in said recipient subject.” Applicants argue that “these functions are the major obstacles with viral techniques and are not problems with chemical or physical techniques...” Applicants go on to argue that the claims of the ‘582 and ‘902 applications do not suggest specific [non-viral] transfected cell preparations as in the instant claims because the prior art taught away from this species. However, it is noted that the instant specification specifically discusses at pages 5-6 that non-viral techniques for gene transfer were known in the art, and that problems exist in both viral and non-viral modes of delivery. The specification further teaches non-viral stable transfection of cell lines in the Examples, see Example 1B, for example. It is also noted that the ‘582 and ‘902 applications have an identical specification to that of the instant specification. As such, it is the Examiner’s position that the ‘582 and ‘902 claims encompass, although not specifically limited to, non-viral *ex vivo* gene therapy, such that these non-viral methods would inherently result in cells that are incapable of the newly claimed functions. Thus, the new claim limitations do not render the claimed invention as an unobvious species of the generic concept of *ex vivo* gene therapy as Applicants contend, rather the new claim limitations are obvious extensions of the ‘582 and ‘902 claims.

Furthermore, it is unclear why Applicants point to art teaching away from non-viral techniques including the belief of the skilled artisan, at the time of filing, that viral transduction was the best method for making transfected cells, since the co-pending claims of the ‘582 and ‘902 applications do not specifically recite viral transduction, and particularly since the specifications of the ‘582 and ‘902 applications teach non-viral transfection of cells.

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With regard to the obviousness-type double patenting rejections of record of the claims over applications or patents other than the '582 and '902, Applicants fail to provide any arguments on the record. It is noted that at the interview with the Examiner on February 7, 2000, Applicants' representative indicated that 2-way obviousness should be applied, and the rejections withdrawn. The Examiner agreed that if 2-way obviousness must be applied to the instant invention and the co-pending or patented inventions, then the rejections should be withdrawn. Please note that Applicants' representative, at any time, on the record or otherwise, failed to show why a 2-way obviousness determination is required. However, after careful review of the 2-way obviousness guidelines presented in the MPEP at Section 804B, the Office holds that the standard of 2-way obviousness should not be applied as the instant application was filed later (June 5, 1995) than the co-pending or patented applications. Two-way obviousness is applied only when Applicants could not have filed the claims in a single application and when there is administrative delay. Note that this decision is not based upon the effective filing dates because it is Applicants' voluntary decision to pursue prosecution of previously rejected claims in a continuation and not the fault of the Office, and, thus, not considered administrative delay.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(f) he did not himself invent the subject matter sought to be patented.

(g) before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it. In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 72-79, 82-84, and 104-106 stand provisionally rejected under 35 U.S.C. 102(f) or (g), or in the alternative, under 35 U.S.C. 103 as being unpatentable over the count and disclosure of the application of the winning party in the interference, which count recites a method of therapy in which cells are transformed (*i.e., in vitro*) and then implanted into the host human or other mammal after selection *ex vivo* (*i.e., in vitro*) which are the presently claimed compositions containing the cells.

Applicants argue that the Examiner has not asserted that the disclosure of the other parties in the interference teach or enable using nonviral *ex vivo* techniques, resulting in cells that are incapable of causing recombination of the DNA sequence with endogenous retroviral sequences and initiating chronic viral infection in the recipient subject. Applicants indicate that this is

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because the Examiner has not considered the previous claim language as distinguishing since it was the Examiner's position that the claim language lacked written description. See pages 27-28 of the Amendment. However, it is held that the new claim limitations do not render the claimed invention as an unobvious species of the generic concept of *ex vivo* gene therapy, rather the new claim limitations are obvious extensions of the claims in the interference count and would be anticipated by, or in the alternative, unpatentable over the teachings disclosed by their specifications.

Conclusion

No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jill Martin whose telephone number is (703)305-2147.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jasmine C. Chambers, can be reached at (703)308-2035.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-0196.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703)308-4242 and (703)305-3014.



Jill D. Martin

Patent Examiner